**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| **VALUE DRUG COMPANY** | : | **CIVIL ACTION** |
| | : | |
| **v.** | : | **NO. 21-3500** |
| | : | |
| **TAKEDA PHARMACEUTICALS, U.S.A., INC.,** | : | |

# MEMORANDUM

**KEARNEY, J.** **February 28, 2023**

A wholesaler purchaser of colchicine claims the brand name patent holder manufacturer conspired with three generic manufacturers to artificially inflate the price for colchicine from 2017 until 2020 by ordering market entry of generic colchicine as part of settling three patent infringement/invalidity cases about to go to trial before Chief Judge Sue L. Robinson. The wholesaler hopes to show the generics enjoyed at least an eighty-five percent likelihood of invalidating the patent which would allow them bring their generic colchicine to market in a few months and reduce the price for colchicine. But, according to the wholesaler, the generic manufacturers instead withdrew their patent invalidity claims right before trial as part of a conspiracy to guarantee their staged entry into the colchicine market while maintaining the patent and precluding later generic manufacturers from entering the market and lowering the price. The wholesaler attempts to prove its theory of antitrust impact by, among other things, having a patent litigation expert, attorney Glen P. Belvis, opine at least one of the generic manufacturers enjoyed an eighty-five percent or greater likelihood of persuading Judge Robinson to invalidate the brand manufacturer's patent.

The brand and generic manufacturers now move to preclude Attorney Belvis from opining the generic manufacturers had an eighty-five percent or greater chance of Judge Robinson invalidating the patent. We held an extensive evidentiary hearing. Counsel focused on Attorney Belvis's methodology employed to find an eighty-five percent or greater likelihood of success for the generic manufacturers. The patent litigation expert could offer little or no methodology. He started his analysis at a seventy-five percent benchmark suggesting the generics enjoyed, from the first day, a seventy-five percent likelihood of invalidating the patent. He then increased the likelihood of success in invalidating the patent by ten percentage points notwithstanding completed discovery informing the parties of the strengths and weaknesses leading to the imminent trial dates (including settling one case on the morning of trial) or without considering the likelihood of success in invalidating this patent specifically in the District of Delaware or before Judge Robinson.

We grant the brand and generic manufacturers' Motion to preclude Attorney Belvis from opining as to an eighty-five or greater percent likelihood of success for the generic manufacturers. We allow him to generally opine regarding a likelihood of success subject to fulsome cross-examination without referencing a numerical figure upon finding:

## I. Findings of Fact

1. We denied Value Drug Company's first motion for class certification without prejudice on November 23, 2022 because Value Drug adduced no evidence supporting the counsel-instructed assumption the generic manufacturers would have persuaded Judge Robinson to invalidate the colchicine patent held by Takeda Pharmaceuticals, U.S.A., Inc.

2. Value Drug retained Glen P. Belvis, Esquire to opine on the generic manufacturers' likelihood of success in persuading Judge Robinson to invalidate the patent as a basic premise for Value Drug's theory of antitrust impact.

3. Attorney Belvis is a thirty-year experienced intellectual property attorney and judges have found him qualified to offer an opinion in patent law and litigation.

4. Attorney Belvis concluded the generic manufacturers had an overall eighty-five percent or greater likelihood of prevailing in the underlying patent litigation against Takeda.

5. Attorney Belvis relied on historical data finding patent owners like Takeda only prevail in patent litigation approximately twenty-five to thirty percent of the time and his own experiences to reach his opinions.

6. Attorney Belvis began his analysis with a starting benchmark of a seventy-five percent chance of success in invalidating patents.

7. He then found the generics had an eighty-five percent overall likelihood of success in the days and weeks before their trials against Takeda after reviewing the case record.

8. Attorney Belvis did not include in his analysis generic success rates in the District of Delaware, generic success rates before Judge Robinson, and the fact patentees (like Takeda) won 60.7% of bench and jury trials across all Districts between 2009 and 2013.

9. Attorney Belvis provides no formula, calculation, or replicable methodology of how and why he adjusts his seventy-five percent success benchmark upward by at least ten percent.

## II. Conclusions of Law

10. Attorney Belvis's opinion the generic manufacturers had an overall eighty-five percent or greater likelihood of persuading Judge Robinson to invalidate the patent is not supported by a reliable methodology.

11. We exclude Attorney Belvis's testimony "the generic defendants had an overall 85% or greater likelihood of prevailing in the underlying [patent] litigation" against Takeda.

12. We allow Attorney Belvis to testify as to his professional opinion regarding the generic manufacturers' likelihood of success without referencing a figure and subject to cross-examination.

## III. Analysis

Colchicine manufacturers Takeda, Amneal Pharmaceuticals LLC, and Watson Laboratories, Inc. move to exclude "[Attorney] Belvis's opinion that the generic defendants had an overall 85% or greater likelihood of prevailing in the underlying [patent] litigation."[1] We reviewed Value Drug's opposition. We preclude Attorney Belvis from opining the generic manufacturers enjoyed an eighty-five percent or greater chance of invalidating Takeda's patent in the imminent trials before Judge Robinson. But he may testify as to his professional opinion regarding the generics' likelihood of success without referencing a percentage.

We must ensure a witness offering an expert opinion possesses adequate "knowledge, skill, experience, training, or education" to support the opinion.[2] We act "as a 'gatekeeper' to ensure that 'any and all expert testimony or evidence is not only relevant, but also reliable.'"[3] Congress, through Rule of Evidence 702, "usually favors admissibility."[4] Rule 702 embodies a "trilogy of restrictions on expert testimony: qualification, reliability[,] and fit."[5] The burden is on the party offering expert testimony to show it meets the standards for admissibility.[6]

Rule 702's trilogy of restrictions "incorporates to some extent a consideration of the dangers, particularly the danger of unfair prejudice, enumerated in" Rule 403.[7] Rule 403 still independently applies to expert testimony.[8] We should exclude evidence under Rule 403 if "its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."[9]

Takeda, Amneal, and Watson argue Attorney Belvis's opinion "the generic defendants had an overall 85% or greater likelihood of prevailing in the underlying [patent] litigation" is unreliable and does not fit with Value Drug's theory the generic manufacturers settled imminent trials they were "certain to win."[10] They do not challenge Attorney Belvis's qualifications.[11] They instead contend Attorney Bevis cherry-picks data and has no replicable methodology for arriving at a minimum ten percent upward adjustment from his unreliable seventy-five percent starting point.[12] Value Drug counters Attorney Belvis's methodology is reliable and judges "routinely" endorse patent litigation experts' use of percentages when testifying to likelihood of success in underlying patent litigations.[13]

We agree with Takeda, Amneal, and Watson. Attorney Belvis's opinion the generic manufacturers enjoyed an eighty-five percent or more likelihood of invalidating Takeda's patent lacks a reliable methodology. We must exclude this quantification absent a reliable methodology consistent with our gatekeeping role under *Daubert*.[14]

Ensuring reliability of expert opinion requires we examine "the process or technique the expert used in formulating the opinion."[15] Attorney Belvis's opinion must be based on "the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'"[16] "In other words, the expert must have 'good grounds' for his belief."[17] In cases

not involving scientific testimony, "the relevant reliability concerns may focus upon personal knowledge or experience."[18]

We are partially guided by our colleagues' earlier analysis of whether patent litigation lawyers, including Attorney Belvis, can testify as experts on the likelihood of success on the merits in a case after the Supreme Court's decision in *F.T.C. v. Actavis, Inc.*[19] We do not agree with Value Drug characterizing the earlier review as judges "routinely" endorsing a percentage of likelihood of success. Especially when the expert cannot offer a methodology.

Judges allow patent litigation experts to offer a specific estimate of the likelihood of success in an underlying patent invalidity trial if they rely on a sufficiently testable methodology.[20] Judge Leinenweber, for example, allowed Attorney Belvis to opine the generic manufacturer had a "greater than 85% overall chance of ultimately prevailing at trial and through appeal."[21] The challenge in *In re Opana* focused on the "85% chance determination falsely denote[d] a level of mathematical precision not present in [Attorney] Belvis's opinion . . . ."[22] The *Daubert* challenge focused less on Attorney Belvis's lack of methodology and more on his translating his percentage into an opinion of "very likely" to win the underlying litigation.[23] Judge Leinenweber held "to the extent the [pharmaceutical] defendants wish to argue that 'very likely' should be a different percentage, they will have the opportunity to do so on cross-examination before the jury."[24]

Judge Burroughs more directly faced the issue we do today in *In re Intuniv Antitrust Litigation* where the patent litigation expert did not provide a methodology for how he arrived at a ninety-five percent likelihood of success in the underlying patent litigation.[25] The expert testified he did not use a formula or equation, but relied upon his experiences and review of the record.[26] Judge Burroughs allowed the expert "to testify as to his professional opinion" but could

not "provide any specific percentage of likelihood, as he provided no concrete methodology for how he reached this figure."[27]

We are also aware of Judge Thrash, Jr.'s analysis allowing a patent litigation expert to opine to a specific percentage based on a detailed methodology in *In re Androgel Antitrust Litigation (No. II)*.[28] The patent litigation expert before Judge Thrash, Jr. identified the average win-rate for a plaintiff in Hatch-Waxman cases, analyzed the generics' case finding it weaker than the average suit, and discounted the average projection to identify the likelihood of success.[29] Judge Thrash, Jr. found the expert identified a methodology and weaknesses in the methodology could be fleshed out on cross-examination.[30]

Our question is whether Attorney Belvis's eighty-five percent or greater opinion should be precluded or instead subject to fulsome cross-examination. We are not facing a "very likely" characterization. We, like Judge Leinenweber, prefer to allow fulsome cross-examination to poke holes in analysis. But we cannot allow an opinion on a numerical likelihood of success absent methodology to enter the jury's consideration. We are persuaded by Judges Burroughs's analysis when facing a specific calculation absent an identified methodology. We cannot find Attorney Belvis employed a reliable or replicable methodology for expressing his opinion "the generic defendants had overall 85% or greater likelihood of prevailing in the underlying [patent] litigation" against Takeda.[31]

We are particularly troubled by Attorney Belvis offering no methodology of how he moves from his seventy-five percent generic win-rate starting benchmark to the eighty-five percent or greater overall chance the generic manufacturers would have been successful in the underlying patent litigation against Takeda before Judge Robinson. Attorney Belvis does not explain how "the significant and multiple problems and weaknesses" with Takeda's case

translates to a ten percent (or greater) increase from a seventy-five percent starting benchmark.[32] Attorney Belvis did not consider contrary data including generic manufacturers' success rates in the District of Delaware, their success rates in front of the vastly experienced Judge Robinson, and patentees (like Takeda) won 60.7% of trials.[33] Comprehensive statistical analysis of district court litigation across the country published approximately one year before Takeda's patent litigation settlements found patentees won 60.7% of bench and jury trials.[34] We cannot identify a reliable or replicable methodology Attorney Belvis used to warrant a ten percent or greater upward adjustment to the benchmark figure, especially given Takeda settled with Watson on the morning of trial.[35] We agree with Judge Burroughs's reasoning the patent litigation expert did not provide a methodology for how he arrived at the statistical figure. We similarly only allow Attorney Belvis to testify as to his professional opinion without reference to overall likelihood of success figure.[36]

We are not persuaded by the reasoning allowing this type of quantified opinion in *In re Opana ER Antitrust Litigation* because we are not concerned with the term "very likely" equating to eighty-five percent overall chance of likelihood of success for the generic manufacturers.[37] The patent holders in *In re Opana Er Antitrust Litigation* did not challenge methodology. They challenged whether the term "very likely" reflects an eighty-five percent likelihood of success.[38] We do not have the same issue here. The primary *Daubert* challenge here focuses on Attorney Belvis's methodology leading him to define the statistical number and goes directly to his reliability. We do not have the same credibility and cross-examination challenges Judge Leinenweber addressed. We also distinguish *In re Androgel Antitrust Litigation (No. II)*.[39] Judge Thrash, Jr. found the expert identified a reliable methodology and weaknesses or flaws could be manifest in cross-examination.[40] We cannot allow a jury to consider Attorney Belvis's

credibility on his statistical figure when we cannot find, after an evidentiary hearing, he identifies a reliable methodology to reach the statistical figure in the first place.

We grant the Defendants' motion to preclude Attorney Belvis from opining the generic manufacturers enjoyed an eighty-five percent or greater likelihood of success in persuading Judge Robinson to invalidate Takeda's colcitrine patent in late 2015 or early 2016.

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[1] ECF Doc. No. 741 at 1.

[2] Fed. R. Evid. 702.

[3] *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (quoting *Kannankeril v. Terminix Int'l Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)).

[4] *Honeywell, Inc. v. Am. Standards Testing Bureau, Inc.*, 851 F.2d 652, 656 (3d Cir. 1988).

[5] *Calhoun v. Yahama Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (quoting *Scheider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003)).

[6] *B. Braun Melsungen AG v. Terumo Med. Corp.*, 749 F. Supp. 2d 210, 222 (D. Del. 2010) (citing *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579, 592 n. 10 (1993); *In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir. 1999)).

[7] *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985).

[8] *See id.*

[9] Fed. R. Evid. 403.

[10] ECF Doc. No. 741 at 1. We do not address whether Attorney Belvis's opinion the generics had an eighty-five percent or greater overall likelihood of success against Takeda "fits" the case because we grant the motion to preclude the quantification of the success based on unreliability.

[11] The first category of restrictions—qualification—requires "that the witness possess specialized expertise." *Pineda*, 520 F.3d at 244 (quoting *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003)). Our Court of Appeals interprets this requirement "liberally." *Id.* "[A] broad range of knowledge, skills, and training qualify an expert." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). We should not "impos[e] overly rigorous requirements of expertise"; "more generalized qualifications" suffice. *Id.*

[12] ECF Doc. No. 741–1 at 5–10 (using the pagination assigned by the CM/ECF docketing system).

[13] ECF Doc. No. 805 at 6–19 (using the pagination assigned by the CM/ECF docketing system).

[14] *Daubert*, 509 U.S. 579 (1993).

[15] *In re Paoli*, 35 F.3d at 742.

[16] *Walker v. Gordon*, 46 F. App'x 691, 694 (3d Cir. 2002) (quoting *In re Paoli*, 35 F.3d at 742).

[17] *Id.* (quoting *In re Paoli*, 35 F.3d at 741–42).

[18] *Betterbox Commc'ns Ltd. v. BB Techs., Inc.*, 300 F.3d 325, 329 (3d Cir. 2002) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999)).

[19] 570 U.S. 136 (2013). *See also In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 188 (S.D.N.Y. 2018) ("[T]estimony by experienced lawyers about the likelihood that patent litigations will succeed or not succeed has been admitted in several post-*Actavis* reverse-payment cases.") (collecting cases).

[20] *In re Intuniv Antitrust Litigation*, No. 16-12653, 2020 WL 5995326, at *11 (D. Mass. Oct. 9, 2020); *see also In re Zetia (Ezetimibe) Antitrust Litig.*, MDL No. 18-2836, 2022 WL 3344191, at *11 (E.D. Va. August 3, 2022) (allowing the patent litigation expert to testify when "the court is assured that [the expert] had a sufficient methodology for arriving at his range of percentages"); *In re Namenda Indirect Purchaser Litigation*, No. 15-6549, 2021 WL 2403727, at *9 (S.D.N.Y. June 11, 2021) (holding patent lawyers expressing opinions as statistics does not mean the expert did not employ any ascertainable or reliable methodology in reaching his conclusions).

[21] *In re Opana ER Antitrust Litigation*, MDL No. 2580, 2021 WL 2291067, at *11 (N.D. Ill. June 4, 2021).

[22] *Id.*

[23] *Id.*

[24] *Id.* at *12.

[25] *In re Intuniv Antitrust Litig.*, 2020 WL 5995326, at *12.

[26] *Id.* at *11.

[27] *Id.*

[28] *In re Androgel Antitrust Litigation (No. II)*, MDL No. 2084, 2018 WL 2984873 (N.D. Ga. June 14, 2018).

[29] *Id.* at *6 .

[30] *Id.* (finding the expert "clearly has a methodology, even if the Defendants believe it to be a weak one.").

[31] ECF Doc. No. 741–3 ¶ 275.

[32] *Id.* ¶ 759.

[33] *See* ECF Doc. No. 741–1 at 9–11 (using the pagination assigned by the CM/ECF docketing system).

[34] Allison, Lemley & Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1790 (2014).

[35] ECF Doc. No. 861, N.T. February 7, 2023 hearing at 92–93.

[36] *In re Intuniv Antitrust Litig.*, 2020 WL 5995326, at *11–12.

[37] *In re Opana ER Antitrust Litig.*, 2021 WL 2291067, at *11–12.

[38] *Id.*

[39] *In re Androgel Antitrust Litig. (No. II)*, 2018 WL 2984873, at *6.

[40] *Id.*